K062828

NOV 27 2006

510(k) SUMMARY

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT:	Helen Lewis
DATE PREPARED:	September 13, 2006
TRADE OR PROPRIETARY NAME:	MOUTHGUARD AND ALIGNER MATERIALS
CLASSIFICATION NAME:	Mouthguard, Unclassified Orthodontic plastic bracket, 872.5470
PREDICATE DEVICES:	The Doctor's® NightGuard™, K053580 EZ Splint / EZ Splint PM, K022809 Align System, K981095

DEVICE DESCRIPTION:

MOUTHGUARD AND ALIGNER MATERIALS are plastic, resin, or laminate materials that are sold for the purpose of making various dental and/or orthodontic appliances such as aligners, bite planes, mouthguards, nightguards, snoring appliances, splints, retainers, repositioners, and temporary bridges. Each material is indicated for the fabrication of orthodontic and dental appliances. Each material is recommended for the construction of specific Class I and II dental devices and appliances. In most cases, the sheets are thermoformed and trimmed to create custom devices or appliances.

INTENDED USE:

MOUTHGUARD AND ALIGNER MATERIALS are indicated for the fabrication of orthodontic and dental appliances.

TECHNOLOGICAL CHARACTERISTICS:

The MOUTHGUARD AND ALIGNER MATERIALS are used in customized devices. All of the components found in MOUTHGUARD AND ALIGNER MATERIALS have been used in legally marketed devices or have been determined safe for dental use. We believe that the prior use of the components in legally marketed devices and the data provided support the safety and effectiveness of MOUTHGUARD AND ALIGNER MATERIALS for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 27 2006

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K062828
Trade/Device Name: Mouthguard and Aligner Materials
Regulation Number: None
Regulation Name: Mouthguard
Regulatory Class: Unclassified
Product Codes: MQC, EBG, NXC, KMY
Dated: November 16, 2006
Received: November 20, 2006

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K062828

Device Name: MOUTHGUARD AND ALIGNER MATERIALS

Indications for Use:

MOUTHGUARD AND ALIGNER MATERIALS are indicated for the fabrication of orthodontic and dental appliances such as aligners, bite planes, mouthguards, nightguards, snoring appliances, splints, retainers, repositioners, and temporary bridges.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R B Betz DDS for Dr Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K062828